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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,193	05/11/2001	Greta Van Den Berghe	6296.204-US	5893

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,193	VAN DEN BERGHE, GRETA	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-14,22-29 and 32-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-14,22-28,37-39,45-61 and 72-85* is/are rejected.

7)☒ Claim(s) *29,32-36,40-44 and 62-71* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 4, 7-14, 22-29 and 32-85 are pending.

Applicant's amendment and response filed June 20, 2005 is acknowledged, and applicants' response has been fully considered. Claims 1, 22 and 23 have been amended. Therefore, claims 1, 4, 7-14, 22-29 and 32-85 are examined.

Withdrawn Claim Rejections - 35 USC § 102

2. The previous rejection of claims 1, 22-25, 27-29, 37-39, 45-46 and 72-73, under 35 U.S.C. 102(b) as anticipated by Shangraw *et al.* (Metabolism 38, 983-989 (1989)), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 10-11 in the amendment filed June 20, 2005.

Withdrawn Claim Rejections - 35 USC § 103

3. The previous rejection of claims 1, 22-25, 27-29, 37-39, 45-46 and 72-73, under 35 U.S.C. 103(a) as being unpatentable over Case *et al.* (Crit. Cure Nurs. Q 22, 75-89 (February 2000)) in view of Gutierrez *et al.* (U. S. Patent 5,885,980), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 11-12 in the amendment filed June 20, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 7-14, 47-61 and 74-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 7-14, 47-61 and 74-85 are indefinite as to whether the patients suffering from CIPNP are diagnosed with CIPNP or not, since the patients who stayed within ICU for several days to weeks for a variety of primary injuries or illnesses and had polyneuropathy may not be diagnosed with CIPNP (see specification, page 1, lines 19-31). The claims are also indefinite as to what effect an amount of the insulin, or an analog or a derivative thereof would have in the treatment. The term "treating said CIPNP" does not reflect the effect of insulin in treating CIPNP. Claims 7-14, 47-61 and 74-85 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Previous rejection of claims 1, 22-28, 37-39, 45-46 and 72-73 under 35 U.S.C. 102(b) as anticipated by Malmberg *et al.* (J. Am. Coll. Cardio. 26, 57-65 (1995)) is maintained. Applicant's arguments have been fully considered, and the response to the argument is shown below.

Malmberg *et al.* teach the use of insulin-glucose infusion followed by multidose insulin treatment in diabetic patients with acute myocardial infarction for three months or longer (Table

4), where infusion of glucose and insulin was carried out in the patients according to the protocol (Table 1) to maintain the blood glucose in the target range of 7 mmol/l (corresponding to 126 mg/dl) to 10.9 mmol/l (about 196 mg/dl). For patients in the infusion group, blood glucose decreased from 15.4 ± 4.1 mmol/l (in the range of 11.3 to 19.5 mmol/l, corresponding to 203 to 351 mg/dl) to 9.6 ± 3.3 mmol/l (in the range of 6.3 to 12.9 mmol/l, corresponding to 113 to 232 mg/dl), and at hospital discharge, blood glucose decreased to 8.2 ± 3.1 mmol/l (in the range of 5.1 to 11.3 mmol/l, corresponding to 92 to 203 mg/dl; Table 3; claims 1, 22-28, 37-39, 45-46 and 72-73). Since the blood glucose level of the patient can decrease from 15.4 ± 4.1 mmol/l (203 to 351 mg/dl) to 113 mg/dl (9.6-3.3 = 6.3 mmol/l) or 92 mg/dl (8.2-3.1 = 5.1 mmol/l) with the treatment, and the diabetic patients with acute myocardial infarction have a high mortality rate are critically ill patients, thus, the teachings in the reference anticipate the claimed method.

Response to Arguments

Applicants indicate the Examiner is using an incorrect conversion factor in converting mmol/l of glucose to mg/dl of glucose. The correct conversion factor is that 1 mmol/l of glucose is approximately equal to 18 mg/dL of glucose (see page 16 of the present application and the Examiner's own citation to Table 1 of Malmberg as teaching a desired blood glucose level of 7-10.9 mmol/l or 126 -196 mg/dl of glucose). Thus, using the correct conversion factor of 1 mmol/l of glucose to 18 mg/dl of glucose, Malmberg's Table 3 shows that infusion of insulin to Malmberg's patients results in a reduction of blood glucose from 15.4 mmol/l (= 277 mg/dl) to 9.6 mmol/l (= 173 mg/dl) or to 8.2 mmol/l (= 148 mg/dl) of glucose. Accordingly, Malmberg cannot be held to anticipate the rejected claims. (page 10 of the response).

Applicants' response has been fully considered, however, the argument is not found persuasive because the Examiner has used the correct conversion factor (1 mmol/l of glucose is equal to 18 mg/dL of glucose) and has presented the range for the mean value ± standard deviation instead of the mean value, e.g., 9.6 ± 3.3 mmol/l is in the range of 6.3 to 12.9 mmol/l, which corresponds to 113 to 232 mg/dl. Since the glucose levels of some patients are reduced from 15.4 ± 4.1 mmol/l (about 203 to 351 mg/dl) to 113 mg/dl (about 6.3 mmol/l) or 92 mg/dl (about 5.1 mmol/l), thus the teachings of the reference meet the criteria of the claims.

New Claim Rejections - 35 USC § 102

6. Claims 4, 7, 12-14, 52-54, 60, 61, 84 and 85 are rejected under 35 U.S.C. 102(b) as anticipated by Shangraw *et al.* (Metabolism 38, 983-989 (1989)) as evidenced by Van Den Berghe (US 2002/0107178).

Shangraw *et al.* teach insulin infusion is used in treating septic patients and nonseptic patients recovering from severe burn injury, where the patients are in the burn intensive care units (page 983, right column; Tables 1 and 2), and the plasma glucose levels of patients maintain between 80 to 120 mg/dl (page 985, right column; Fig. 3; claims 4, 7, 12-14, 52-54, 60, 61, 84 and 85). Although Shangraw *et al.* do not specifically indicate the septic patients are diagnosed with CIPNP, these septic patients, who stayed in the ICU for several days to weeks, would inherently develop CIPNP, since Van Den Berghe indicates CIPNP occurs in about 70% of patients having systemic inflammatory response syndrome (SIRS), and CIPNP develops in patients that are treated within ICU and have a variety of primary injuries or illness such as sepsis and multiple organ failure (paragraph [0003]).

Claim Objection

7. Claims 29, 32-36, 40-44 and 62-71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusions

8. Claims 1, 4, 7-14, 22-28, 37-39, 45-61 and 72-85 are rejected; and claims 29, 32-36, 40-44 and 62-71 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CMK
August 10, 2005

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER